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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/934,680	08/23/2001	Duncan W. McBranch	8971-017-27	8385

7590 04/17/2006  
Supervisor, Patent Prosecution Services  
PIPER MARBURY RUDNICK & WOLFE LLP  
1200 Nineteenth Street, N.W.  
Washington, DC 20036-2412

EXAMINER

LU, FRANK WEI MIN

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 04/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b>	Application No.	Applicant(s)	
	09/934,680	MCBRANCH ET AL.	
	Examiner	Art Unit	
	Frank W. Lu	1634	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED \_\_\_\_\_ FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☒ The reply was filed after the date of filing a Notice of Appeal, but prior to the date of filing an appeal brief. The Notice of Appeal was filed on 22 March 2006. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ They raise the issue of new matter (see NOTE below);
- (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: \_\_\_\_\_.
- Claim(s) objected to: \_\_\_\_\_.
- Claim(s) rejected: 1,3-5,7-13,22,25 and 26.
- Claim(s) withdrawn from consideration: 14-21.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached office action.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_
13. ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***ADVISORY ACTION***

1. The proposed amendments filed on March 22, 2006 have been fully considered and entered.

***Response to Arguments***

In page 2, second paragraph bridging to page 3, last paragraph of applicant's remarks in PRE-APPEAL BRIEF REQUEST FOR REVIEW, applicant argues that: (1) "Coull does not provide any motivation to substitute Heller's DNA with peptide nucleic acids. Coull does not disclose or suggest that peptide nucleic acids are equivalent to other types of nucleic acids or could be substituted therefor"; (2) in view of column 6, lines 1-13, 25, 26, 52, and 53 of Coull *et al.*, "[O]ne reviewing Coull would not conclude that Heller's nucleic acids could be easily or reliably substituted by Coull's peptide nucleic acids. Coull teaches that such a substitution would be at best unpredictable"; and (3) "[T]he Examiner also ignores Heller's teachings why one need not use anything other than RNA or DNA".

These arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection. First, Coull *et al.*, do provide any motivation to substitute Heller's DNA with peptide nucleic acids. In page 8 of the office action mailed on September 22, 2005, the examiner clearly stated "[O]ne having ordinary skill in the art would have been motivated to do so because incorporation of PNA into the recognition element of the chemical moiety recited in claim 1 would enhance stability of the chemical moiety recited in claim 1 and increase half-life of the chemical moiety recited in claim 1 (see Coull *et al.*, column 5, last paragraph) since PNA is not sensitive to nuclease digestion (see Coull *et al.*, column 4, second paragraph), and

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would enhance to form a more stable complex between the recognition element of the chemical moiety recited in claim 1 and a target nucleic acid (see Coull *et al.*, column 6, last paragraph)". Second, although applicant argues that biological, structural, and physico-chemical differences between PNA probes and standard nucleic acid probes may lead to unpredictable results, applicant does not provide an evidence to show why a chemical moiety comprising a sequence of peptide nucleic acid is unpredictable. According to applicant's philosophy, the function of peptide nucleic acid is unpredictable. However, it is not a case here because the function of peptide nucleic acid is well known in the art (see the patent from Coull *et al.*). Third, Heller does not teach that "one need not use anything other than RNA or DNA" as suggested by applicant. Although Heller does not teach to use peptide nucleic acid, he teaches that nucleic acid can be a modified nucleic acid having modifiable backbone structure to produce different properties (see columns 6 and 7) (example; normally negatively charged DNA can be made in a neutral form) and it is known that peptide nucleic acid is a modified nucleic acid in a neutral form (see Coull *et al.*, column 6). Thus one reviewing Heller's disclosure would be motivated to use a modified nucleic acid that has modifiable backbone structure and is in a neutral form.

II. In page 4, first paragraph of applicant's remarks in PRE-APPEAL BRIEF REQUEST FOR REVIEW, applicant argues that "[Neither Chen, Woodrum, nor Chick cure the contrary teachings of Heller and Coull with respect to the broadest claim, Claim 1. As such, they are not sufficient to sustain a rejection of the claims that depend from Claim 1".

This argument has been fully considered but it is not persuasive toward the withdrawal of

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the rejection because the references from Chen *et al.*, Woodrum, nor Chick *et al.*, are not used to cure the contrary teachings of Heller and Coull *et al.*, (see the office action mailed on September 22, 2005).

III. In page 4, second and third paragraphs of applicant's remarks in PRE-APPEAL BRIEF REQUEST FOR REVIEW, applicant argues that "[T]he rejected claims are all drawn to a chemical moiety, in which the fluorescent moiety, peptide nucleic acid sequence recognition element, and property altering element are tethered together, in a particular order. In contrast, Whitten claims 1-18 are drawn to: (1) a composition, in which the fluorescent moiety is either not tethered or is tethered in a different order from what is presently claimed; (2) a kit, in which the fluorescent moiety is not tethered or is completely separated; and (3) a method of using the Whitten composition. The Applicants fail to see how the present claims, drawn to a chemical moiety with parts tethered together in a particular order, can obviously overlap with the Whitten claims, drawn as they are to a composition, a kit, and a method".

These arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection. First, fluorescent moiety taught by claims 1-10 of US Patent No. 6,743, 640B2 is not tethered in a different order from what is presently claimed (see claims 1-10 of US Patent No. 6,743, 640B2 and claim 1 of this instant application). Second, applicant appears to agree that fluorescent moiety taught by claims 1-10 of US Patent No. 6,743, 640B2 is tethered (see above applicant's arguments) and applicant has no evidence to show that fluorescent moiety taught by claims 1-10 of US Patent No. 6,743, 640B2 is tethered in a different order from what is presently claimed.

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2. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)272-0735.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Frank Lu  
Primary Examiner  
April 12, 2006



**FRANK LU**  
**PRIMARY EXAMINER**